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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,799	11/21/2005	Dieter Herrmann	2970-125	7706

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
05/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,799	HERRMANN ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *September 19, 2005 (preliminary amdt.)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12* is/are rejected.

7)☒ Claim(s) *1-7 and 13-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2005; 11/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

This application has been filed with informal drawings acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

Note to applicant: the preliminary amendment filed September 19, 2005 indicated that an amendment to the specification was present at "page 2," but for reasons unknown to examiner "page 2" is absent from the scanned documents in the USPTO file wrapper database. Resubmission of the missing page in a subsequent amendment is respectfully requested.

No claims have been cancelled, claims **4-9** have been amended, the disclosure has not been amended, and no new claims have been added as per the preliminary amendments filed September 19, 2005. Two Information Disclosure Statements (2 IDSs) filed September 19, 2005 and November 21, 2005 have been received with all cited references and made of record.

Claims **1-19** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **8-11** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the inhibiton of the growth of human lung carcinoma by a single active ingredient, does not reasonably provide enablement for the treatment of any other neoplastic disease condition or for the administration a pharmaceutical composition wherein there is more than one active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The instant pharmaceutical composition clim and method of treatment claims are directed to compositions containing multiple active ingredients, and to methods of treating all "malignant tumors" by administration of a single active ingredient, or by administration of multiple active ingredients wherein the additional active ingredients are only defined generically in claim **11**.

B. The nature of the invention: The invention is directed to conjugates of certain purine nucleotides and glycerides, pharmaceutical compositions thereof, the administration of said conjugates to treat tumors, and a method of making said conjugates.

C. The state of the prior art: The prior art of record does not disclose references other than applicant's priority documents and related publications wherein the instant subject matter has been disclosed.

D. The level of one of ordinary skill: One of ordinary skill would be knowledgeable concerning how to make nucleotide conjugates of the kind claimed and how to determine an effective dosage for medicinally appropriate administration thereof in the treatment of tumors.

E. The level of predictability in the art: In view of the small amount of biological data provided the level of predictability is very low.

F. The amount of direction provided by the applicant: Only a single example of a single active ingredient claimed herein has been provided wherein a single neoplastic disease condition has been effectively treated.

G. The existence of working examples: This subject is described in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in view of the minimum amount of biological test data provided.

Claims **1-3, 5 and 12-14** are objected to because of the following informalities:

In claim **1** at lines 4 and 9, the Markush preambles are superfluous and incorrect because of the absence of the required subsequent term -- and --. The "or' terms left in place are sufficient.

In claim **1** at line 11, there is a typographical error (a subscript number not shown as a subscript).

In claims **2 and 3** at line 2, there is a typographical error (a subscript number not shown as a subscript).

The structure at line 3 of claim **5** is missing bonds and functional groups (major repairs needed).

In coaim **12** at line 17, the chemical structure is in need of some repairs to insure that the arrangement of atoms is clearly and unequivocally presented.

Claim **12** is missing terminal punctuation.

In claim **13** the term "f-amylate" is a misspelling of -- t-amylate --.

In claim **14** the term "f-butanol" is a misspelling of -- t-butanol --.

Appropriate correction is required.

Claims **8 and 11-12** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **8** the term "at least one" is indefinite because no upper boundary defining the maximum number of active ingredients has been specified in the remainder of the claim. Deletion of the noted term or other appropriate action is respectfully requested.

In claim **11** the term "other anticancer agents" is incomplete because this generic term has not been further defined by a listing of the other particular agents intended to be included within the metes and bounds of the claim.

In claim **12** at lines 19, the term "hindered potassium base" is incomplete because it is unclear what particular class of basic substances are berg referred to by the noted term

In claim **12** at lines 23-24, the term "conditions to provide ... substitution reaction" is incomplete because the particular conditions have not been specified with particularity. See also this same claim at line 29 ("activated form" not completely defined) and line 35 ("conditions that provide for aminolysis") wherein the same general kind of problem reoccurs.

Claims **13-19** are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims **1-7** are objected to as containing various minor errors in claims **1-3 and 5** the correction of which would render the claims allowable.

Claims **8-12** would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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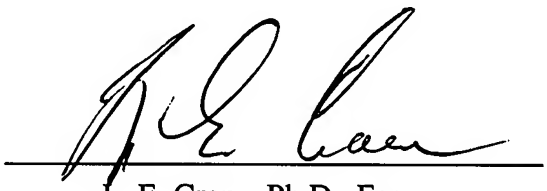
05/14/2007



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